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	APPLICANT: Braun and Sutton		
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U.S. PATENT DOCUMENTS

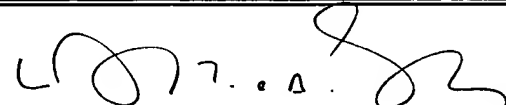
EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
401	6,320,037	11/20/01	Braun et al.	536	23.7	—

FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

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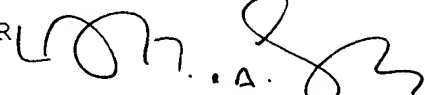
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Form PTO 149 US Department of Commerce Patent and Trademark Office DEC 26 2001 PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO: P-PM 4966 APPLICANT: Braun and Sutton	SERIAL NO. 09/966,608
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101	Blaser et al., "Patients With Active Crohn's Disease Have Elevated Serum Antibodies to Antigens of Seven Enteric Bacterial Pathogens," <u>Gastroenterology</u> , 87:888-894 (1984). ✓
	Brandwein et al., "Spontaneously Colitic C3H/HeJBir Mice Demonstrate Selective Antibody Reactivity to Antigens of the Enteric Bacterial Flora," <u>J. Immunol.</u> , 159:44-52 (1997). ✓
	Bregenholt et al., T-cell Transfer and Cytokine/TCR Gene Deletion Models in the Study of Inflammatory Bowel Disease," <u>APMIS</u> , 105:655-662 (1997). ✓
	Cellier et al., "Mycobacterium Paratuberculosis and Mycobacterium Avium Subsp. <i>Silvaticum</i> DNA Cannot be Detected by PCR in Crohn's Disease Tissue," <u>Gastroenterol. Clin. Biol.</u> , 22:675-678 (1998). ✓
	Chang et al., "Identification of Herpesvirus-Like DNA Sequences in AIDS-Associated Kaposi's Sarcoma," <u>Science</u> , 266:1865-1869 (1994). ✓
	Chiba et al., "No Mycobacterium Paratuberculosis Detected in Intestinal Tissue, Including Peyer's Patches and Lymph Follicles, of Crohn's Disease," <u>J. Gastroenterology</u> , 33:482-487 (1998). ✓
	Clarkston et al., "Role of Mycobacterium Paratuberculosis in Crohn's Disease," <u>Dis. Colon Rectum</u> , 41:195-199 (1998). ✓
	Cocito et al., "Paratuberculosis," <u>Clinical Microbiology Reviews</u> , 7(3):328-345 (1994). ✓
	Cong et al., "CD4+ T Cells Reactive to Enteric Bacterial Antigens in Spontaneously Colitic C3H/HeJBir Mice: Increased T Helper Cell Type 1 Response and Ability to Transfer Disease," <u>J. Exp. Med.</u> , 187:855-864 (1998). ✓
	Dalwadi et al., "Identification of a Novel IBD-Associated Microbial Agent by Representational Difference Analysis," <u>Gastroenterology</u> , 116(4): A696 AGA Abstracts (1999).

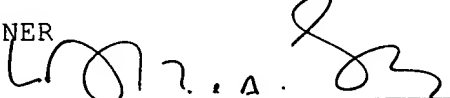
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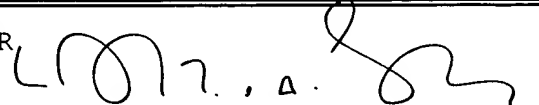
50	Davidson et al., "Antibodies to Maize in Patient With Crohn's Disease, Ulcerative Colitis and Coeliac Disease," <u>Clin. Exp. Immunol.</u> , 35:147-148 (1979).
	Del Prete et al., "Detection of <i>Mycobacterium Paratuberculosis</i> in Stool Samples of Patients With Inflammatory Bowel Disease by IS900-Based PCR and Colorimetric Detection of Amplified DNA," <u>J. Microbiol. Methods</u> , 33:105-114 (1998).
	Dianda et al., "T Cell Receptor- $\alpha\beta$ -Deficient Mice Fail to Develop Colitis in the Absence of a Microbial Environment," <u>Am. J. Pathol.</u> , 150:91-97 (1997).
	El-Zaatari et al., "Characterization of a Specific <i>Mycobacterium Paratuberculosis</i> Recombinant Clone Expressing 35,000-Molecular-Weight Antigen and Reactivity With Sera From Animals With Clinical and Subclinical Johne's Disease," <u>Journal of Clinical Microbiology</u> , 35(7):1794-1799 (1997).
	Elsaghier et al., "Antibodies to <i>Mycobacterium Paratuberculosis</i> -Specific Protein Antigens in Crohn's Disease," <u>Clin. Exp. Immunol.</u> , 90:503-508 (1992).
	Fidler et al., "Specific Detection of <i>Mycobacterium Paratuberculosis</i> DNA Associated With Granulomatous Tissue in Crohn's Disease," <u>Gut</u> , 35:506-510 (1994).
	Gui et al., "Two-Year-Outcomes Analysis of Crohn's Disease Treated With Rifabutin and Macrolide Antibiotics," <u>J. Antimicrob. Chemother.</u> , 39:393-400 (1997).
v	Herfarth et al., "Interleukin 10 Suppresses Experimental Chronic, Granulomatous Inflammation Induced by Bacterial Cell Wall Polymers," <u>Gut</u> , 39:836-845 (1996).

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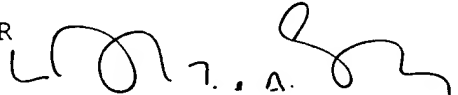
LM	Hornquist et al., "G α i2-Deficient Mice With Colitis Exhibit a Local Increase in Memory CD4 ⁺ T Cells and Proinflammatory Th1-Type Cytokines," <u>J. Immunol.</u> , 158:1068-1077 (1997). ✓
	Janowitz et al., "The Role of the Fecal Stream in Crohn's Disease: An Historical and Analytic Review," <u>Inflamm. Bowel. Dis.</u> , 4:29-39 (1998). ✓
	Knoflach et al., "Serum Antibodies to Cow's Milk Proteins in Ulcerative Colitis and Crohn's Disease," <u>Gastroenterology</u> , 92:479-485 (1987). ✓
	Kühn et al., "Interleukin-10-Deficient Mice Develop Chronic Enterocolitis," <u>Cell</u> , 75:263-274 (1993). ✓
	Metcalf, "Is Measles Infection Associated With Crohn's Disease?," <u>Brit. Med. J.</u> , 316:166 (1998).
	Mombaerts et al., "Spontaneous Development of Inflammatory Bowel Disease in T Cell Receptor Mutant Mice," <u>Cell</u> , 75:275-282 (1993). ✓
	Morrissey et al., "CD4 ⁺ T Cells That Express High Levels of CD45RB Induce Wasting Disease When Transferred Into Congenic Severe Combined Immunodeficient Mice. Disease Development is Prevented by Cotransfer of Purified CD4 ⁺ T Cells," <u>J. Exp. Med.</u> , 178:237-244 (1993). ✓
	Moss et al., "Polymerase Chain Reaction Detection of <i>Mycobacterium Paratuberculosis</i> and <i>Mycobacterium Avium</i> Subsp <i>Silvaticum</i> in Long Term Cultures From Crohn's Disease and Control Tissues," <u>Gut</u> , 33:1209-1213 (1992). ✓
	Podolsky, "Lessons From Genetic Models of Inflammatory Bowel Disease," <u>Acta Gastro-Enterol. Belg.</u> , 60:163-165 (1997). ✓
V	Powrie et al., "Inhibition of Th1 Responses Prevents Inflammatory Bowel Disease in <i>scid</i> Mice Reconstituted With CD45RB ^{hi} CD4 ⁺ T Cells," <u>Immunity</u> , 1:553-562 (1994). ✓

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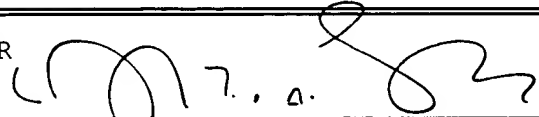
50	Prantera et al., "An Antibiotic Regimen for the Treatment of Active Crohn's Disease: A Randomized, Controlled Clinical Trial of Metronidazole Plus Ciprofloxacin," <u>Am. J. Gastroenterol.</u> , 91:328-332 (1996). ✓
	Rudolph et al., "Ulcerative Colitis and Adenocarcinoma of the Colon in α_{12} -Deficient Mice," <u>Nat. Genet.</u> , 10:143-149 (1995).
	Rudolphi et al., "Polyclonal Expansion of Adoptively Transferred CD4+ $\alpha\beta$ T Cells in the Colonic Lamina Propria of Scid Mice With Colitis," <u>Eur. J. Immunol.</u> , 26:1156-1163 (1996). ✓
	Sadlack et al., "Ulcerative Colitis-Like Disease in Mice With a Disrupted Interleukin-2 Gene," <u>Cell</u> , 75:253-261 (1993). ✓
	Sanderson et al., "Mycobacterium Paratuberculosis DNA in Crohn's Disease Tissue," <u>Gut</u> , 33:890-896 (1992). ✓
	Seibold et al., "pANCA Represents a Cross-Reactivity to Enteric Bacterial Antigens," <u>Journal of Clinical Immunology</u> , 18(2):153-160 (1998). ✓
	Sendid et al., "Specific Antibody Response to Oligomannosidic Epitopes in Crohn's Disease," <u>Clin. Diag. Lab. Immunol.</u> , 3:219-226 (1996). ✓
	Sonnenberg, "Occupational Distribution of Inflammatory Bowel Disease Among German Employees," <u>Gut</u> , 31:1037-1040 (1990). ✓
	Thomas et al., "Controlled Trial of Antituberculous Chemotherapy in Crohn's Disease: A Five Year Follow Up Study," <u>Gut</u> , 42:497-500 (1998). ✓
▼	Vannuffel et al., "Occurrence, in Crohn's Disease, of Antibodies Directed Against a Species-Specific Recombinant Polypeptide of <i>Mycobacterium paratuberculosis</i> ," <u>Clinical and Diagnostic Laboratory Immunology</u> , 1(2):241-243 (1994). ✓

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50	Wayne et al., "Immunoglobulin A (IgA) and IgG Serum Antibodies to Mycobacterial Antigens in Crohn's Disease Patients and Their Relatives," <u>Journal of Clinical Microbiology</u> , 30(8):2013-2018 (1992).
	Weiner, "Oral Tolerance: Mobilizing the Gut," <u>Hospital Practice</u> , 53-58 (1995).
	Weiner et al., "Oral Tolerance: Immunologic Mechanisms and Treatment of Animal and Human Organ-Specific Autoimmune Diseases by Oral Administration of Autoantigens," <u>Ann. Rev. Immunol.</u> , 12:809-837 (1994).

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